

AUG 13 2008

K081459

CUSA Selector NXT Ultrasonic Surgical Aspirator Module 510(k) Summary

Submitter's Name and Address:

Integra Radionics
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Contact Person and Telephone Number:

Kevin J. O'Connell
Director Regulatory Affairs and Quality Assurance
Integra Radionics, Inc.
Tel.: (781) 565-1227

Date Summary was Prepared: May 12, 2008.

Name of the Device:

Trade Name: CUSA Selector NXT Ultrasonic Surgical Aspirator

Common Name: Ultrasonic Surgical Aspirator

Classification Name: Instrument, Ultrasonic Surgical
Product Code: LFL

Classification Panel: General and Plastic Surgery

Substantial Equivalence:

The CUSA Selector NXT Ultrasonic Surgical Aspirator is intended for use in surgical procedures where fragmentation, emulsification, and aspiration of soft tissue and hard (e.g. bone) is desirable. Such functions are within the indications of use for the predicate devices. The technological characteristics are similar to those found in the following predicate devices: Selector Ultrasonic Surgical Aspirator with Bone Tip cleared via 510(k) K071669 on August 17, 2007, Selector Quantum Ultrasonic Surgical Aspirator cleared via 510(k) K042277 on September 29, 2004, and Selector Integra Ultrasonic Surgical Aspirator System cleared via 510(k) K021989 on September 13, 2002.

The CUSA Selector NXT Ultrasonic Surgical Aspirator consists of two components: System Console and Service Module. The System Console operates the full functions of the aspirator, but does not have an on-board aspiration source. The Service Module is an

add-on that provides an integrated system look with a fully independent aspiration source. The product is being updated to improve usability and control technology within the system. It will utilize the existing set of Selector handpieces.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 13 2008

Integra Radionics, Inc.
% Mr. Kevin J. O'Connell
Director, RA/QA
22 Terry Avenue
Burlington, Massachusetts 01803-2516

Re: K081459

Trade/Device Name: CUSA Selector™ NXT Ultrasonic Surgical Aspirator System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: LFL
Dated: May 21, 2008
Received: May 27, 2008

Dear Mr. O'Connell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Mr. Kevin J. O’Connell

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health’s (CDRH’s) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH’s Office of Surveillance and Biometric’s (OSB’s) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K 081459

Device Name: CUSA Selector™ NXT Ultrasonic Surgical Aspirator System

Indications For Use:

The CUSA Selector™ NXT Ultrasonic Surgical Aspirator System is indicated for use in surgical procedures where fragmentation, emulsification and aspiration of soft and hard (e.g. bone) tissue is desirable, including Neurosurgery, Gastrointestinal and affiliated organ surgery, Urological surgery, Plastic and Reconstructive surgery, General surgery, Orthopedic surgery, Gynecological surgery, Thoracic surgery, Laparoscopic surgery and Thoracoscopic surgery.

PRESCRIPTION USE X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 801 Subpart C)

**(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON
ANOTHER PAGE IF NEEDED)**

Concurrence of CDRH, Office of Device Evaluation (ODE)



**(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices**

CUSA Selector NXT Ultrasonic Tissue Ablation System 510(k)
510(k) Number K 081459

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